

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS  
REPORTED IN D. D. N. J. NOS. 4881-4920

*Adulteration*, Section 501 (a) (1), the article consisted in part of a filthy substance; Section 501 (a) (2), the article had been prepared and packed under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, and its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality and purity fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

*New-drug violation*, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED  
ACCORDING TO DIRECTIONS

4881. *Hormonex*. (F. D. C. No. 38280. S. No. 30-185 M.)

QUANTITY: 233 1-oz. btls. at St. Louis, Mo.

SHIPPED: 6-15-55, from Paris, Tenn., by Golden Peacock, Inc.

LABEL IN PART: (Btl.) "Hormonex Beauty Serum Use only 8 drops daily Mitchum Distributors Fifth Ave. New York Just 8 drops of Hormonex Beauty Serum gives your skin the maximum daily allotment of natural female hormones. Use dropper top to measure 8 drops into the palm of one hand. Spread over the face and throat with the fingertips of other hand. Contains 150,000 I. U. Natural estrogenic hormones."

LIBELED: 8-15-55, E. Dist. Mo.

CHARGE: 502 (j)—the article, when shipped, was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling since the directions for use, which appeared on the bottle label, provided for the daily application of approxi-

mately 1,500 International Units of estrogens as estrone over an extended and indefinite period of time, an amount which could cause injury to health.  
DISPOSITION: 9-23-55. Default—destruction.

#### NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

4882. Broiler Pre-Mix. (F. D. C. No. 38248. S. No. 16-247 M.)

QUANTITY: 10 50-lb. bags at Seattle, Wash.

SHIPPED: 5-27-55, from Pasadena, Calif., by Ray Ewing Co.

LABEL IN PART: (Bag) "A Ray Ewing Custom Mix \* \* \* Broiler Pre-Mix Guaranteed Potencies \* \* \* Nicarbazin, Grams 90.80 Per Pound."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 7 percent of the declared amount of nicarbazin.

LIBELED: 7-27-55, W. Dist. Wash.

CHARGE: 502 (a)—the label statement "Guaranteed Potencies \* \* \* Nicarbazin, Grams 90.80 Per Pound" was false and misleading; 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11-30-55. Default—destruction.

4883. Serpina tablets. (F. D. C. No. 38244. S. No. 24-721 M.)

QUANTITY: 1 unlabeled drum containing 5,000 tablets at Seattle, Wash.

SHIPPED: 3-30-55, from Bombay, India, by Himalaya Drug Co.

RESULTS OF INVESTIGATION: The article was shipped from India in a bulk container labeled in part "Serpina Each tablet contains 4 mg. of the total alkaloids of Rauwolfia serpentina (Benth)."

LIBELED: 7-26-55, W. Dist. Wash.

CHARGE: 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11-30-55. Default—destruction.

#### DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4884. Halazone tablets and Dramamine tablets. (F. D. C. No. 38184. S. Nos. 30-203/4 M.)

QUANTITY: 59 btls. containing 1,000 tablets of *Dramamine*, and 1,100 cases, 300 100-tablet btls. each, of *halazone* at Memphis, Tenn.

SHIPPED: The articles were shipped in interstate commerce to Memphis, Tenn.; however, the name of the shipper and the date of shipment are unknown.

LABEL IN PART: (Btl.) "1,000 Tablets \* \* \* Dramamine Brand of Dimenhydrinate 100 mg. Caution: to be dispensed only by or on the prescription of a physician," "Tablets Water Purification Individual (Halazone) \* \* \* Each tablet contains P-Sulfonedichloramido Benzoic Acid (1/16 Grain) Sodium Carbonate Sodium Chloride Boric Acid," "Halazone Tablets (p-sulfonedichloramido benzoic acid 0.004 gm.; sodium borate and chloride)," or "Water Purification Tablets \* \* \* Each Tablet Contains 0.004 Gm. (1/16 Grain) of Halazone."